

December 20, 2004

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

(Docket Nos. 1996P-0418, 1997P-0197, 1998-0203, and 2000N-0504)

Dear Sir and Madam:

I am writing to comment on the Food and Drug Administration's proposed rule on *Salmonella Enteritidis* in shell eggs. Michael Foods Egg Products Company as Crystal Farms, M. G. Waldbaum and Papetti's has gross sales in excess of \$1.2 B of which 80% of the sales are in eggs and egg products. Fresh eggs account for approximately 5%, while pasteurized liquid, precooked egg entrees, hard boiled eggs, dried eggs, in shell pasteurized eggs, frozen eggs and inedible animal byproducts make up the remaining 95%. As a company we own approximately 13.5 million birds in our own facilities or as contracts and purchase eggs or liquid from another 25 million birds.

As a company we are burdened with regulation from city, county, state, federal, international regulations. Even when the aim of regulation is good, the burden of complying can be heavy. Michael Foods respectfully urges the FDA to minimize the additional burden by:

1. **Reviewing the current state and private egg quality assurance programs** with the idea of incorporating the proven parts into the FDA regulations. Producers who voluntarily comply to equivalent programs should either be exempted or considered in compliance with FDA regulations. The industry although competitive is very progressive and willing to do what is necessary to maintain a positive image when given effective, scientific based direction.
2. The costs on the egg producer at \$82 M compared to \$8M for the FDA are still very high and need to be minimized. The Agricultural Marketing Service, for instance, already inspects some of our facilities in cooperation with the state agency. **We recommend the use of such individuals.** The AMS and the states are knowledgeable of the egg industry, using them will avoid diverting FDA employees away from homeland security, import inspections and other work.
3. The benefits of **listening and incorporating research existing from poultry scientists and industry leaders** will speed the implementation of any program and avoid some of the obvious pitfalls written into the current proposal.

The FDA proposed "new" prevention program has some basic flaws either not understood or ignored which may be of value. These comments are made with much experience over nearly 15 years of struggles with SE.

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Chick testing in the form of box paper testing is a good program but in fact we have been testing for 12 years or more and had one flock problem and that was early in the 90's. Commercial hatcheries and breeders are doing a great job. Leave the emphasis for breeder salmonella for the chick to the NPIP program other than the **NPIP testing form with the chicks**.

**Pullet houses do need to be tested** on an individual flock program especially when contract growers have no farm history of testing. The farm flora is characteristic of the rodents, people, bio-security, and birds previously on the farm. Multiage farms, outside raised birds and single age farms can have SE. There is no predictability without testing.

Biosecurity - A bio-security program is important. On-farm people are one of the less essential parts once on the farm. Hands, clothes and shoes are possibly the most important when people enter from the outside especially if they have contacted other birds or animals. Within a complex the spread will take place almost no matter what is done. Movement of birds, either intentional or unintentional, within the complex is an important way of spreading the bacteria to other houses. Untreated egg shells and /or old equipment are other ways of spreading SE from the outside into the house. Not discussed is the role of pallets, divider boards, and egg flats which can carry egg meats with bacteria from one contract farm to another contract farm. These materials are also the same materials that carry AI from flock to flock. People from the packing area can then carry the agent to the birds. **The bio-security program needs to be reviewed with appropriate poultry scientists** as some of the program is currently inappropriate and unusable.

Rodent, flies and other pests are an important way of spreading SE within a complex and from outside. **Mice are the worst carrier** since they walk in the feed trough and leave their droppings. Other pests are carriers but not as essential since they do not contact the birds or the feed as much. Flies and beetles are mechanical carriers. The control of any pest is an essential part of the bio-security program. Cleanliness is also important as misplaced equipment and dust and dirt provide harborage for mice.

We feel it is **not essential to determine the presence of flies**. The assumption is that all farms have flies. The requirement is an activity without direct benefits. In the case of state or local requirements or where a farm has a problem the spot cards are a method to determine the numbers and, therefore, the control program.

Cleaning and disinfection- Removal of dust and contamination reduces the bacterial load within a house. The easiest way is to remove it as a dry product. Washing is not essential as it creates wet conditions for bacterial growth. We do wash and disinfect our pullet houses and have considered it an essential part of a viral control for Marek's Disease.

During the winter when birds have been removed from the house the water lines will freeze. The cost of heating the house with gas is prohibitive. **A requirement to wash is not practical in our climate.**

Our farms had several direct experiences which show control of SE without washing is as effective as washing. Early in our program we washed a complex of 3 houses and replaced the birds. In 35 weeks the birds were again shedding SE. Vaccination was the key to ultimate removal of the SE. Another 20-house plus complex had one positive isolate in 10 years even though no house has ever been washed, no known exposure and an excellent rodent program. Vaccination and isolation were required to keep the SE from spreading. **A SE control program**

**requires consistent testing and logical long term management of the conditions using vaccination.**

The cost of washing a belted house as a hot wash was slightly less than \$10,000. The house required 5 to 6 people working back to back shifts for 2 weeks. The difficulty was getting the belts clean and then the mucky water ran onto the belts below. The floors were not sloped for removing water from the building. As the water dried it became a soupy mess that was scooped, brushed and scraped. The house was never totally cleaned and was left with a rotten manure odor. Luckily the temperatures were more moderate and the fans could be operational.

Refrigeration is a proven acceptable procedure however, in the breaking industry contract **producer eggs are moved to the plant at higher temperatures to increase the amount of egg white yield, improve peeling of hard cooked eggs and improve the quality of pasteurized eggs.** At 45 degrees the rule of thumb is a 2% loss of albumen which will be attached to the shell and be lost to inedible. Plants usually do not operate on the weekends so the 36 hour rule will cause a loss in yield of stored eggs. **An alternative program** might be to allow temperatures above or at 65 degrees for 72 hours with a reduction to 55 and then 45 at 7 days. Those temperature conditions allow for the natural elevation of pH in the egg white which is proven to improve shell removal after hard cooking and minimizes heat induced cloudiness in whites of pasteurized shell eggs. These temperatures would be more applicable for eggs in transition and destined for processing with minimum negative impact on safety of pasteurized or hard cooked eggs. Many contract producers do not have the ability to hold temperatures of 45 due to inadequate cooler space or equipment.

**Excusing refrigeration for small producers exaggerates the problem of no testing.** If the eggs are sold to a public establishment then the establishment must have refrigeration and the producer must have refrigeration. Data is available that indicates a low potential for growth in the first week.

**Testing is a necessary practice to determine the presence or absence of SE.** The methods need to be repeatable, simple and direct using least cost methods. Our current costs are 1/3 to 1/2 of the reported proposed program because of less numbers, and less culture media yet our isolations of salmonella have been in the 80% range over a 10 year period. The techniques are simple and straight forward. The cost of egg testing is about \$1.00 per egg mostly due to the labor. We use no pre-enrichment. Our techniques in earlier days have yielded significant isolations in houses environmentally positive.

**The time of testing is "luck of the draw".** Our testing has been at 30 to 35 weeks, 40 to 45 weeks, ten weeks after molt and end of lay. More recently our cultures at 80 weeks to 85 weeks have been used as end of lay. The end of lay test needs to be done early enough that it allows the pullets to be vaccinated prior to entering the lay house. All have worked well.

Egg testing is usable but very cumbersome and time consuming if done right. . Only question we have is who is going to do the testing as most states do not have the facilities? A reputable producer such as ours with the lab facilities and the approved techniques could be allowed to test the eggs based on previous testing protocols. **Egg testing within 24 hours is not a realistic possibility** just from a logistics point of view even with a lab on the premises. Most outside labs will not have media made and ready especially if it is an infrequent need. People have to be scheduled and eggs need to be collected and transported to the facility. The emphasis on third

party is good to a point, however, we do not trust others with our business and we know our business.

**Vaccination is an acceptable and effective procedure in controlling SE** in a complex or single house when other bio-security measures such as rodent control practiced. We have managed a large farm that was historically negative through a positive house introduction with one vaccination of the next flock and dry cleaning and disinfection. The adjoining houses were tested clean several times. The current complex is still negative.

The SE cycle in any house includes the passage between primarily 2 hosts, the chicken and the mouse. The reduction of one affects the other directly. The cats, dust, people, flies and beetles are a reflection of the mice and chicken and chicken status. SE phage 8 and 13a in our conditions has been a labile organism as it does not appear to live but 3 to 4 weeks outside the host.

The vaccination improves the protection of the egg and reduces the shedding in the bird which reduces the number of organisms available to the mice and eventually the mice die or reduce the shed of organisms from the droppings. Vaccination in or just before molt has converted a positive house to negative however, mortality because of handling was much higher.

**Vaccines should not be mandated.** We had over 100 flocks at one time and SE was found in 2 farms and 4 flocks. It would be a shame to mandate vaccines to be used in every flock. The cost of vaccinating is 10 to 13 cents a bird. From a technical point of view vaccines are the only sure way to provide immunity to the bird. We currently have our own contracts that are all negative.

**Record keeping should be kept to a minimum.** A written plan should account for 1 page of a document. This program will be accomplished only if it is simple. Planning, a few details, person responsible, training and monitoring results and actions taken are the essential parts. **The necessary data are the testing results and actions.**

The requirement for one person for a farm is nice but in the case of contract production where birds are owned by someone else the use of a central person is more likely to direct the essential parts of the program and the farm owner or manager is trained to complete the essential parts of the program. I think the "must" is the complicating word. In reality **the program will be a joint activity.** On multiple complex farms a person may have responsibility on a farm but the overall program may be dictated by someone with full responsibility.

**Safe egg handling practices and preparation practices should be mandated for highly susceptible populations.** Pasteurized egg products are safe. Why place the choice in the hands of someone with no understanding of the risk of choosing raw eggs verses safe pasteurized eggs when it could be removed?

3,000 bird limit- if the real direction for the program is to reduce the incidence in humans then the limit must be lower. The real fact is that below 3,000 birds there is not enough manpower to test all the flocks. Organic producers are increasing. These farms are usually small producers. The birds are allowed access to the ground which increases the potential to be exposed to mice and other animals.

In the eyes of the CDC, all isolations are equally important and there is no definition about who and where the eggs come from. The whole egg industry gets a black eye if one is reported as a case. **The obvious answer to the problem is to require vaccination of the below 3000 flocks and excuse them from the testing part of the program.**

**Should the producer be required to register?** No. The addition of another program of registration is just another burden. If this is an SE program the FDA check should be no more than a check for compliance not a controlling of other peoples time for hours and days. Unexpected visits are not appropriate as a respect for other people. The reality is that no one can hide what you want to see in 24 hours. I feel that the registration will ensure a loss of privacy for the producer and is unnecessary for the success of the program.

FDA may "perform environmental sampling and collect eggs for testing" in suspect outbreaks. The costs of testing should not be borne by the producer and the results are a matter of record at the time of completion **to the producer first**. In the case of a difference between previous testing and the test by the FDA a third sample will be necessary prior to diversion of eggs. **The FDA could collect duplicate samples and send to a lab acceptable to the producer.**

Molting is a fact of production. Economics dictate a molt program because of the cost of the pullet. Vaccination has shown an improvement in the SE shedding into the egg on a short and long term basis.

**Testing for *Salmonella enteritidis* in the feed is not a necessary part of the SE program.** We have tested meat and bone meal which is the major problem ingredient for salmonella presence for 12 years and some 1100 samples. Our tests have never recorded a positive SE sample with about 37% salmonella recovery. We have found one group D which was not identified as an SE.

**If the methodology is too dictatorial there is more resistance to compliance and improvement in methodology is stifled. (Keep it simple.)**

One practical example of methodology improvement is in the use of milk. Milk is a great media if the cultures are started in a short period of time such as 8 to 24 hours at cooler temperatures. We have found in the summer and with samples shipped up to 48 hours the bacteria in the swabs diluted with milk grow and inhibit salmonella from being isolated. We use chicken broth and find it much better. In samples taken which require less than 4 hours before starting the cultures a saline or water or peptone broth is adequate.

The methodology proposed as routine testing is a research project in itself and very expensive. **Our simplified program has given very good results for 12 years.** TT broth for 24 hours incubation, streak on BG with novobiocin and XLT4 media for 24 hours and pick 5 colonies for TSI and one out of 5 to lysine. Test the isolates by salmonella and group D antiserum. Test positives by flagella test. **The 80% isolation rate is a credit to sample collection technique and methodology.**

Eggs are broken into a bag and incubated for 4 or 5 days, 1 ml transferred to 10 ml TT for 24 hours and streaked with a swab on BG with novobiocin and XLT4. Colonies are picked as usual.

**The proposed diversion of eggs to breakers is of concern because breaking locations are not always convenient to the producer and the resulting product may not be acceptable to the purchaser or consumer.**

The cost of the program suggested in the Federal Register is very expensive. RV, peptone broth and bismuth plates are all very expensive. The numbers of plates and broths are extremely detailed, numerous and not necessary. This testing is not a research project. **The goal is to reduce the SE in the chicken house not test it to death.**

**Essential points:**

SE is normally not a hardy bacterium. SE requires birds and mice to stay alive in the environment. Once the source is eliminated the bacteria in the environment will disappear and it will also disappear in the birds and the mice. From our experience the passing of infection between birds and mice is the important method of maintaining the house level of infection.

Washing and disinfection are only point reductions and difficult to maintain without other activities such as vaccination.

Vaccination is the only long term benefit the bird has to prevent re-infection and reduce the level of shed into the egg and the environment. It should not be the only part of the program.

Mice control is a mechanical program to reduce the level of exposure.

The monitoring needs to be simple, and practical. **There is no need to find the last isolate first.** find the major number of isolates and then build the rest of the program to reduce the low number of isolates, for instance, with vaccination.

The FDA needs to work with the producer. The producer needs to have the "monkey" on his back but the monkey doesn't have to be the FDA. SE is the monkey. SE reduction is a long term project not to be solved tomorrow.

Sincerely,



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